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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,117	08/06/2003	Daniel E. Couto	GTC-207	2070

31904 7590 12/16/2004
GTC BIOTHERAPEUTICS, INC.
175 CROSSING BOULEVARD, SUITE 410
FRAMINGHAM, MA 01702

EXAMINER

MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/635,117

Applicant(s)

COUTO ET AL.

Examiner

Robert B Mondesi

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10, 12-54, 59-61 and 71 is/are rejected.
- 7) ☒ Claim(s) 11, 55-58 and 70 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>September 17, 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to amendment filed September 24, 2004. **Claim 71** is new. **Claims 7-9** have been cancelled. **Claims 1-6 and 10-71** are currently pending and are under examination.

Withdrawal of Objections and Rejections

The objection of the specification because of informality is withdrawn.

There is no rejection under 35 U.S.C § 112, first paragraph.

The rejection of **claims 1-70** under 35 U.S.C § 112, second paragraph is withdrawn.

Maintenance of rejections

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-10, 14-19, 20-54, 59-61 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by van Reis et al. United States Patent 5,256,294.

This rejection was explained in the previous Office action.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Reis et al. United States Patent 5,256,294 in view of Kuni hau et al.

This rejection was explained in the previous Office action.

Response to applicant's arguments

The applicants assert that as amended claim 1 recites several elements not present or suggested in any of the teachings of van Reis including :

A) usage of milk as feedstream; and

B) primary usage of ultrafiltration as opposed to microfiltration; and
in claim 71:

C) cell lysate as feed stream

The applicants assert further that neither of the elements A-C above are disclosed in the van Reis reference and therefore the rejection of claims 1-6 and 7-10 are overcome.

In response the examiner would like to state that this is not found persuasive because van Reis et al. do indeed teach the mentioned limitations.

Van Reis et al. state that an aspect of the invention provides a process for separating species of interest having the size of about 0.1 to 10 microns through a filtration membrane having the pore size that separates the said species (column 5, lines 26-30). According to the definition of microfiltration by van Reis et al., microfiltration is a process of filtering by forcing liquids through a screen with pores between the sizes of 0.1 to 10 microns (column 9, lines 8-11). So clearly, van Reis et al. teach the limitation of microfiltration. Furthermore, van Reis et al. state that examples of preferred species include mammalian cells and microorganisms such as bacteria, fungi, and yeast (both cells and microorganisms being amenable to microfiltration techniques) (column 8, lines 37-42). Moreover, van Reis et al. state, the process is applicable to a

wide range of biological molecules, eg., proteinaceous products of fermentation with natural or genetically engineered microorganisms, high molecular weight antibodies and cellular secretions (column 15, lines 42-47). According to the Webster English dictionary, milk is **a white nutritious liquid secreted by mammalian cells** and hence taught by van Reis et al. as a feed-stream.

The examiner would like to also point out that **claims 18-53 and 59-69** are merely optimizations of a known method that could have been scientifically and logically arrived at by a person skill in the art and therefore do not provide any specific limitations that contribute to the novelty of the invention over the prior art.

Conclusion

Claims 1-6, 10, 12-54, 59-61 and 71 are not allowed.

Claims 11, 55-58 and 70 are objected to for depending from a rejected base claim.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

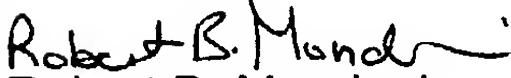
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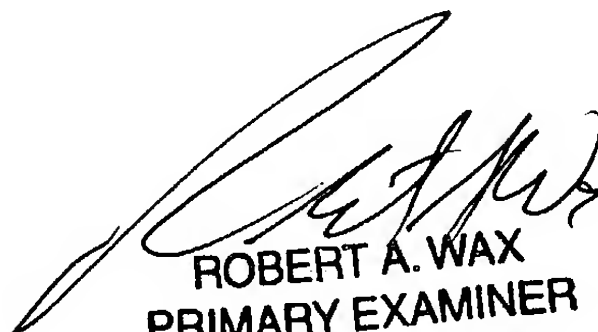
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert B. Mondesi
Patent Examiner
Group 1653
12-12-04


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